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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,377	11/15/2001	Carlo Gambacorti-Passerini	45922/241203 (5865-2)	4010

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EXAMINER	
SZPERKA, MICHAEL EDWARD	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/008,377	GAMBACORTI-PASSERINI ET AL.	
	Examiner	Art Unit	
	Michael Szperka	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *10 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *2 and 5-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3 and 4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/3/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-21 are pending.

1. Applicant's election Group I, claims 1, 34, and 4, and the peptide species of SEQ ID NO:1 in the reply filed on November 10 2004, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Since Applicant indicated at the start of the response to the restriction requirement that Group I consisted of claims 1, 3, and 4, and because of the fact that there is no claim 34 currently in this application, the Examiner believes the inclusion of claim 34 and the exclusion of claim 3 as part of Group I to be a typographical error. As such, the Examiner will examine the claims that were set forth as Group I in the initial restriction requirement dated August 30, 2004, namely claims 1, 3, and 4 as they read on the elected peptide species of SEQ ID NO:1.

Claims 2 and 5-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Claims 1, 3, and 4 are under examination.

2. Citation number 9, Passoni et al., found on applicant's form 1449 submitted on July 30, 2002, has been considered but has been lined through because no date was provided for the reference. The examiner has determined the appropriate date for this reference and it has been indicated on the form 892 that accompanies this office action.

3. The disclosure is objected to because of the following informalities:

A) The word medium is misspelled in line 16 of page 12.

B) The word further is misspelled in line 19 of page 19.

C) Line 10 of page 3 contains the sequence SLAMLDLLHV that is not identified by a SEQ ID number. Applicant is required to amend the specification to indicate that this sequence is SEQ ID NO:2.

D) Line 15 of page 7 indicates that the peptide of SEQ ID NO:2 is amino acids 376-85 of the native ALK sequence, while line 21 of page 7 indicates that SEQ ID NO:2 is amino acids 375-386.

E) Interferon-γ is customarily abbreviated as IFN-γ, not as INF-γ as can be found on page 23, line 7 of the specification.

Appropriate correction of all of the above is required.

Applicant is also required to review the instant application for compliance with the requirements of applications which contain sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821-1.825. If the instant application does not have an appropriate SEQ ID NO: for each

disclosed sequence, then Applicant must comply with the Sequence Rules as set forth in 37 CFR 1.821-1.825.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claimed peptides are generated by the activity of the proteasome when it degrades the anaplastic lymphoma kinase (ALK) protein molecules present in the cell. These peptides are then available for presentation to the immune system on MHC class I molecules. Therefore, these peptides are products of nature. Amendment of the claim to recite "An isolated and purified ..." would remove this rejection.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Passoni et al. (Blood, 2000, vol. 96, no. 11, part 1, page 338a, see entire abstract).

Passoni et al. teach that overexpression of anaplastic lymphoma kinase (ALK) is responsible for the disease anaplastic large cell lymphoma (ALCL). Passoni et al. also teach that ALK is a tumor-associated antigen, and that peptides from ALK can be used to trigger a CTL response *in vitro* (see entire abstract, particularly paragraphs 1-3 and 6). The decapeptide sequence SLAMLDLLHV is disclosed as binding HLA-A*0201. This peptide was then used to generate a CTL line that secreted interferon-γ and lysed peptide pulsed, HLA-matched target cells (see particularly the fifth paragraph of the abstract).

It is noted that the indicated publication date of this reference is November 16, 2000. However, it has been indicated to the examiner that a printed copy of this material was available at the Dahlgren Memorial Library at Georgetown University on November 14, 2000. This information has been indicated on a form 892. A physical copy of the abstract and date received stamp for this journal from Georgetown

University was not available for mailing with this office action. Upon the receipt of this printed material by the examiner, a copy will be promptly provided to Applicant.

Therefore the prior art anticipates the claimed invention.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Passoni et al. (Blood, 2000, vol. 96, no. 11, part 1, page 338a, see entire abstract) in view of Cantrell, U.S. Patent No. 4,877,611 (see entire document).

The teachings of Passoni et al. have been discussed above. They differ from the claimed invention in that Passoni et al. do not explicitly indicate that the tumor-associated antigen that corresponds to the peptide of SEQ ID NO:1 was present in a pharmaceutical composition.

Cantrell teaches that tumor-associated antigens are useful for the treatment of cancer when in the form of pharmaceutical compositions and vaccines (see entire document, particularly the abstract, column 2 lines 41-60, column 3, lines 33-48 and claim 1). The tumor-associated antigen and the adjuvant are prepared for use as a vaccine with a pharmaceutically acceptable carrier such as physiological saline or oil droplet emulsions (see particularly column 7, lines 6-46). Such a vaccine can then be employed in a clinical setting for the treatment of tumors in patients (see particularly column 2, lines 41-60 and the paragraph that spans columns 7 and 8). Cantrell indicated that his vaccine formulation should be used with a wide variety of tumor-associated antigens (see particularly page 3, lines 43-48 and claim 1).

Therefore a person of ordinary skill in the art at the time the invention was made would have been motivated to use the tumor associated antigen disclosed by Passoni et al. in a vaccine composition disclosed by Cantrell for the purpose of treating patients diagnosed with anaplastic large cell lymphoma.

10. No claims are allowable.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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December 8, 2004

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